IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants:	Connell et al.
Appl. No.:	09/711,240
Conf. No.:	6987
Filed:	November 13, 2000
Title:	METHOD AND APPARATUS FOR KIDNEY DIALYSIS
Art Unit:	1723
Examiner:	J. Drodge
Docket No.:	ALT-5604D CON II of DIV III

Commissioner for Patents
Washington, DC 20231

APPELLANTS' REPLY BRIEF

Sir:

Appellants submit this Reply Brief in support of the Notice of Appeal filed on July 11, 2002. This Appeal is taken from the Final Rejection dated April 11, 2002.

I. INTRODUCTION

Appellants submit this Reply Brief in response to the Examiner's Answer dated October 15, 2002 pursuant to 37 C.F.R. § 1.193(b)(1). Appellants respectfully submit the Examiner's Answer has failed to remedy the deficiencies noted in Appellants' Appeal Brief filed on September 11, 2002 for the reasons set forth below. Accordingly, Appellants respectfully request that the rejection of the pending claims be reversed.

II. REPLY TO EXAMINER'S ANSWER

A. No basis exists in the cited prior art for combining Lichtenstein with Kerns and/or Rubalcaba.

Appellants previously argued that the cited prior art neither teaches nor suggests combining the hemodialysis machine of Lichtenstein with the touch screen of Kerns and/or Rubalcaba. *See, e.g.*, Appellants' Brief, Section VII. A. 2, beginning at page 5. Contrary to the Examiner's alleged basis for such a motivation to combine, Lichtenstein identifies a problem inherent in remote monitoring of medical devices and treatments that Lichtenstein solved using a computer. Specifically, the "central monitoring system" referred to in Lichtenstein is a computer

system, not a touch screen, which can be hospital-wide with separate, stand-alone units. Lichtenstein, column 31, lines 12-18. Such a system provides no hint whatsoever of the desirability of controlling a hemodialysis machine using a user interface configured as a touch screen.

The specific advantage identified by Lichtenstein is a "reduction in the frequency of necessary personnel intervention" for widely scattered medical procedures through remote monitoring as performed by the computer "central monitoring system." Lichtenstein column 31, lines 28-30. The critical feature of such remote monitoring concerns the hospital computer network, not any specific type of user interface. Lichtenstein, column 31, lines 34-50. The presence or absence of a touch screen on individual medical devices is immaterial to this specific advantage because the advantage is achieved solely by the computer itself.

Hence, Lichtenstein does not motivate the person of ordinary skill in the art of hemodialysis to search for new user-interfaces.

Further, Rubalcaba and Kerns specifically identify the problems of confusion of data due to detachment and reattachment of multiple, identical infusion modules. This problem is not addressed by Appellants' claims. Rubalcaba and Kerns provide no hint of hemodialysis machine problems addressed by Appellants' claims. Furthermore, as noted above, because Lichtenstein provides no motivation to add a touch screen user interface to a hemodialysis machine, the person of ordinary skill would not be motivated in any way to combine either Rubalcaba or Kerns with Lichtenstein to yield the subject claims.

Indeed, Rubalcaba and Kerns simply provide mechanisms for delivering medicaments to a patient's blood system. Administering drugs intravenously is not the same as performing an extracorporeal blood treatment, such as hemodialysis, and provides no teaching or suggestion of the problems associated with hemodialysis or how to solve them. To contend otherwise is simply hindsight.

Moreover, Appellants invented a certain way of controlling a hemodialysis machine that, as subsequent events have proven, is highly effective. Such hindsight was not available to Lichtenstein, Kerns, or Rubalcaba and is not available now to the Examiner to serve as a basis for the claim rejections. Regardless of the nature of Lichtenstein's computer, the Examiner has engaged in hindsight reconstruction of the various combinations recited in the subject claims. Examiner's Answer, page 8, ¶ 2.

Lichtenstein provides no hint whatsoever that a user interface for the Lichtenstein device can be a touch screen or anything like a touch screen. No further alterations to hemodialysis machine controls, or improvements to user interfaces, are required or even contemplated by this reference.

In response to Appellants' argument that the problems inherent in modular drug infusion units (such as those disclosed by Kerns and Rubalcaba) are not addressed by Lichtenstein, the Examiner asserts that Lichtenstein does address such problems. Examiner's Answer, page 9, ¶ 1. However, the "modules" referred to in Lichtenstein are essentially disposable blood-tubing sets ("modular vessel structures") and are a far cry from the pump modules disclosed in Kerns and Rubalcaba.

Furthermore, the mention of tubing modules in Lichtenstein provides no disclosure, suggestion, or hint whatsoever of combining a touch screen with a hemodialysis machine, why such a combination would be beneficial or desirable in a hemodialysis machine, how a touch screen could incorporate the complex controls and displays necessary in a hemodialysis machine, what operating parameters of a hemodialysis machine could be controlled or displayed using a touch screen, or how data concerning any operating parameters of a hemodialysis machine could be displayed or changed using a touch screen. Thus, because neither Kerns nor Rubalcaba is concerned with the particular problems with which Appellants were involved in deriving the claimed invention, the Examiner has improperly combined Kerns or Rubalcaba with Lichtenstein. Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 881, 45 U.S.P.Q.2d 1977, 1981 (Fed. Cir. 1998).

Moreover, a great amount of innovation was required, by persons such as Appellants, to adapt touch screens, and the systems with which they were to be used, for use as satisfactory user-machine interfaces. As argued extensively by Appellants in the record, the user interface disclosed in Rubalcaba and Kerns is highly tailored for its specific end-use application. *See* Appellant's Brief, Section VII. A. 2, beginning at page 5, especially pages 6-7. Only the great hindsight afforded by having been a witness to the explosion of touch screen use over the last ten years would lead one to conclude that Rubalcaba or Kerns renders obvious all use of touch screens since 1991. Indeed, the Rubalcaba, Kerns and Lichtenstein patents were filed three, five, and twelve years, respectively, before Appellants' effective filing date of April 19, 1991.

B. In maintaining the obviousness rejection, the Examiner has misrepresented the evidence of secondary considerations offered by Appellants and has failed to give this evidence adequate weight.

The Examiner argues that Appellants' hemodialysis machine is deemed to be, in large part, a result of many factors other than the touch screen, and is hence not commensurate with the scope of the claims on appeal. Examiner's Answer, page 13, ¶ 3 to page 14. Appellants do not dispute that the System 1000 incorporated a number of new features. However, the law does not require that evidence in support of secondary considerations of nonobviousness be directed only to the specific features in the claims at issue. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1273, 20 U.S.P.Q.2d 1752-1753 (Fed. Cir. 1991); Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 719, 21 U.S.P.Q.2d 1053, 1057-1058 (Fed. Cir. 1991). Rather, the law requires only that Appellants show a sufficient nexus between the claimed invention and the secondary considerations asserted by Appellants. *See* Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387,1392, 7 U.S.P.Q.2d 1222, 1226 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 956 (1988). Appellants have shown the required nexus. The evidence of record clearly shows that the key reason for the System 1000 receiving several major design awards, achieving commercial success, and being the subject of intensive copying by competitors was the inclusion of a touch screen. Appellants' Brief, Section VII. B. 1, beginning at page 13.

Further, Appellants already have shown that much of the electrical and computer software aspects of Appellants' system are due directly to the provision of a touch screen, which replaced a very large number of conventional discrete controls and displays (all of which otherwise would have to be accommodated somewhere on the front panel of the machine). However, the Examiner has provided no showing of why the "extensive development" renders the subject claims obvious. Rather, the noted extensive development logically lends support to a proper conclusion that the subject claims are not obvious from the cited art.

As Appellants have discussed in the record, the hemodialysis industry is strongly driven by costs, especially U.S. government reimbursements for end-stage-renal disease treatments. Appellants' hemodialysis machine, manufactured according to the subject claims, did not achieve commercial success simply because it had a different appearance. Rather, as shown extensively in the record and as evidenced by the Sadler Declaration, the commercial success of Appellants' machine was due to the inclusion of the touch screen which substantially reduced

operating costs (e.g., by substantially reducing training time, and by enabling the safe inclusion of multiple dialysis-treatment modalities such as variable sodium, bicarbonate, and ultrafiltration without the need to purchase separate machines for these modalities). Furthermore, after Appellants commenced marketing the System 1000, all of Appellants' competitors begun marketing respective hemodialysis machines including a touch screen. The one feature common to all these machines is the touch screen. In the highly competitive hemodialysis industry, Appellants' competitors perceived the System 1000 as a highly successful machine that posed a genuine risk to the market share of Appellants' competitors. In configuring their respective machines to compete with the System 1000, Appellants' competitors included the one feature they perceived as key to the System 1000's success – the touch screen.

Even if Appellants' touch screen were disclosed and enabled by Kerns and Rubalcaba, then touch screens existed at least as early as 21 January 1986 (the filing date of Kerns), and a long-felt need to adapt touch screens for use with hemodialysis machines existed from that same date. Appellants solved this long-felt need. The fact that Appellants' competitors quickly and readily copied Appellants' invention further demonstrates that Appellants' invention was not obvious in light of the cited prior art.

The touch screen included with Appellants' claimed hemodialysis machines is not same as the specialized calculator of Kerns and Rubalcaba. Appellant's Brief, Section VII. A. 2, beginning at page 5; *see esp.*, pages 8-9. However, if the Examiner's argument is accepted, then all touch screens are the same and their utilization with any of various machines is routine.

This conclusion is incorrect. If touch screens had been readily adaptable to all medical systems on the priority date, then a hemodialysis machine having a touch screen would have appeared in the market soon after the first touch screens were available to inventors of medical devices. Based on Kerns, touch screens were available to such inventors at least as early as 1986. Therefore, a need for a hemodialysis machine having a touch screen existed at least five years before Appellants solved this long-felt need with their claimed invention.

III. CONCLUSION

For the reasons stated above, the Examiner has not adequately refuted Appellants' contention that (a) the Examiner failed to establish a *prima facie* case of obviousness, and (b) the Examiner improperly maintained the rejection under 35 U.S.C. § 103(a) based on hindsight analysis. However, even if the Examiner did happen to establish a *prima facie* case for

obviousness, Appellants have placed in the record substantial evidence of secondary consideration of nonobviousness. The Examiner has failed to adequately refute this evidence.

The Examiner's errors should be reversed and the pending claims should be allowed.

Respectfully submitted,

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